APPIC (2016-719)

SERIOUS ADVERSE EVENT REPORT

Mail all pages of the reports to: sae.invent.ctc@erasmusmc.nl, fax +31 (0)10 70 41 028

Patient information

Patient study number |__|__|__|__|

Year of birth |__|__|__|__|

CTC staff only

SAE sequence number |__|__|__|__|-|__|__|__|

Report reviewed by

……..

Date review |___||___||_____|

Report information

Hospital ……

Person reporting the SAE ……

Type of report ☐ Initial report ☐ Follow up report ☐ Final report

Date of initial report [dd/mm/yyyy] |___||___||_____|

Date of follow up report [dd/mm/yyyy] |___||___||_____| |___||___||_____| |___||___||_____|

Date of final report [dd/mm/yyyy] |___||___||_____|

Serious Adverse Event information

Adverse Event Term ……

Diagnosis of Adverse Event in a single term; if no diagnosis is available yet, please provide the most relevant sign or symptom

Date onset AE [dd/mm/yyyy] |___||___||_____|

Date AE became Serious [dd/mm/yyyy] |___||___||_____|

Reason AE is Serious |__| 1= death 2= life-threatening 3= (prolongation of) hospitalization 4= significant / persistent disability 5= congenital anomaly / birth defect 6= other medically important condition

Date of hospitalization [dd/mm/yyyy] |___||___||_____|

Date of discharge [dd/mm/yyyy] |___||___||_____|

Severity of AE [CTCAE grade] |__|

(Highest grade observed)

SAE description and comments - describe the course of events, include dates and results of tests / procedures / actions taken /dates of discharge (for final report: outcome of adverse event, test result etc.)

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Treatment Arm and Phase

Treatment arm |__| 1= arm A (short 48 hours course of intravenous antibiotics) 2= arm B (standard 5 days course of intravenous antibiotics)

Protocol phase during / after which the SAE occurred |__| 0= Postoperative, before discharge 1= Postoperative, after discharge

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Pat. Study number: |__|__|__|__| Date of report |___||___||_____|

□ Initial report □ Follow up report □ Final report

Trial medication

Please specify details of the trial medication/treatment that the patient received in this protocol phase:

Trial medication[1]	**Total daily dose** (please add units)	**Date first administration** (during this protocol phase)	**Date last administration** (Date last dose prior to SAE)	**Relationship to SAE**[2]	**Action taken as a result of this SAE**[3]
|__| ……..	|___||___||_____|	|___||___||_____|	|__|	|__|
|__| ……..	|___||___||_____|	|___||___||_____|	|__|	|__|
|__| ……..	|___||___||_____|	|___||___||_____|	|__|	|__|

[1] Trial medication		[2] Relationship to SAE	[3] Action taken	
0= Not applicable	2= Cefuroxim	0= unrelated	0= none	3= interrupted
1= Metronidazol	3= Ceftriaxon	1= likely	1= next dose reduced	4= discontinued
			2= delayed	5= restarted

Possible Causes of SAE other than Trial medication

Please specify if there are circumstances other than trial medication that may have contributed to the SAE or could help explain the SAE

Disease under study (including progression) |__| 0= No 1= Yes

Medical condition(s) |__| 0= No 1= Yes, specify below

Any relevant past or current medical disorders (not disease under study), allergies, surgeries that could help explain the SAE

Concomitant medication(s) |__| 0= No 1= Yes, specify below

Other |__| 0= No 1= Yes, specify below

Specification:……

……

……

Outcome of SAE

|__| 1= resolved*

2= ongoing

3= death *(caused by SAE)***

4= ongoing at death *(death due to another cause)***

5= ongoing closed *(because stable situation reached)*

* Date SAE resolved [dd/mm/yyyy] |___||___||_____|

** Date of death [dd/mm/yyyy] |___||___||_____|

** Cause of death ……

Action taken regarding the SAE ……

Signature for report – the (sub) investigator should always review and sign at least the final report

Date |___||___||_____| **Name:** …… **Signature** ……

Date |___||___||_____| **Name:** …… **Signature** ……

Date |___||___||_____| **Name:** …… **Signature** ……

Date |___||___||_____| **Name:** …… **Signature** ……

Date |___||___||_____| **Name:** …… **Signature** ……